

makes annual payments under the State plan of at least \$5,000,000 must establish certain minimum written policies relating to the Federal False Claims Act.

(7) Section 1902(a)(77) of the Act requires that States comply with provider and supplier screening, oversight, and reporting requirements described in section 1902(kk)(1) of the Act.

(8) Section 1902(a)(80) of the Act prohibits payments for items or services provided under the State plan or under a waiver to any financial institution or entity located outside of the United States.

(9) Section 1902(kk)(7) of the Act requires States to enroll physicians or other professionals that order or refer services under the State plan.

(10) Section 1903(i) of the Act prohibits FFP for amounts expended by MCOs or PCCMs for providers excluded by Medicare, Medicaid, or CHIP, except for emergency services.

(11) Section 1903(m) of the Act establishes conditions for payments to the State for contracts with MCOs.

(12) Section 1932(d)(1) of the Act prohibits MCOs and PCCMs from knowingly having certain types of relationships with individuals and entities debarred under Federal regulations from participating in specified activities, or with affiliates of those individuals.

(b) *Basic rule.* As a condition for receiving payment under a Medicaid managed care program, an MCO, PIHP, PAHP, PCCM or PCCM entity must comply with the requirements in §§ 438.604, 438.606, 438.608 and 438.610, as applicable.

(c) *Applicability.* States will not be held out compliance with the following requirements of this subpart prior to the dates noted below so long as they comply with the corresponding standard(s) in 42 CFR part 438 contained in the CFR, parts 430 to 481, edition revised as of October 1, 2015:

(1) States must comply with §§ 438.602(a), 438.602(c) through (h), 438.604, 438.606, 438.608(a), and 438.608(c) and (d), no later than the rating period for contracts starting on or after July 1, 2017.

(2) States must comply with § 438.602(b) and § 438.608(b) no later than

the rating period for contracts beginning on or after July 1, 2018.

#### § 438.602 State responsibilities.

(a) *Monitoring contractor compliance.* Consistent with § 438.66, the State must monitor the MCO's, PIHP's, PAHP's, PCCM's or PCCM entity's compliance, as applicable, with §§ 438.604, 438.606, 438.608, 438.610, 438.230, and 438.808.

(b) *Screening and enrollment and revalidation of providers.* (1) The State must screen and enroll, and periodically revalidate, all network providers of MCOs, PIHPs, and PAHPs, in accordance with the requirements of part 455, subparts B and E of this chapter. This requirement extends to PCCMs and PCCM entities to the extent the primary care case manager is not otherwise enrolled with the State to provide services to FFS beneficiaries. This provision does not require the network provider to render services to FFS beneficiaries.

(2) MCOs, PIHPs, and PAHPs may execute network provider agreements pending the outcome of the process in paragraph (b)(1) of this section of up to 120 days, but must terminate a network provider immediately upon notification from the State that the network provider cannot be enrolled, or the expiration of one 120 day period without enrollment of the provider, and notify affected enrollees.

(c) *Ownership and control information.* The State must review the ownership and control disclosures submitted by the MCO, PIHP, PAHP, PCCM or PCCM entity, and any subcontractors as required in § 438.608(c).

(d) *Federal database checks.* Consistent with the requirements at § 455.436 of this chapter, the State must confirm the identity and determine the exclusion status of the MCO, PIHP, PAHP, PCCM or PCCM entity, any subcontractor, as well as any person with an ownership or control interest, or who is an agent or managing employee of the MCO, PIHP, PAHP, PCCM or PCCM entity through routine checks of Federal databases. This includes the Social Security Administration's Death Master File, the National Plan and Provider Enumeration System (NPPES), the List of Excluded Individuals/Entities (LEIE), the System for

Award Management (SAM), and any other databases as the State or Secretary may prescribe. These databases must be consulted upon contracting and no less frequently than monthly thereafter. If the State finds a party that is excluded, it must promptly notify the MCO, PIHP, PAHP, PCCM, or PCCM entity and take action consistent with § 438.610(c).

(e) *Periodic audits.* The State must periodically, but no less frequently than once every 3 years, conduct, or contract for the conduct of, an independent audit of the accuracy, truthfulness, and completeness of the encounter and financial data submitted by, or on behalf of, each MCO, PIHP or PAHP.

(f) *Whistleblowers.* The State must receive and investigate information from whistleblowers relating to the integrity of the MCO, PIHP, PAHP, PCCM, or PCCM entity, subcontractors, or network providers receiving Federal funds under this part.

(g) *Transparency.* The State must post on its Web site, as required in § 438.10(c)(3), the following documents and reports:

(1) The MCO, PIHP, PAHP, or PCCM entity contract.

(2) The data at § 438.604(a)(5).

(3) The name and title of individuals included in § 438.604(a)(6).

(4) The results of any audits under paragraph (e) of this section.

(h) *Contracting integrity.* The State must have in place conflict of interest safeguards described in § 438.58 and must comply with the requirement described in section 1902(a)(4)(C) of the Act applicable to contracting officers, employees, or independent contractors.

(i) *Entities located outside of the U.S.* The State must ensure that the MCO, PIHP, PAHP, PCCM, or PCCM entity with which the State contracts under this part is not located outside of the United States and that no claims paid by an MCO, PIHP, or PAHP to a network provider, out-of-network provider, subcontractor or financial institution located outside of the U.S. are considered in the development of actuarially sound capitation rates.

**§ 438.604 Data, information, and documentation that must be submitted.**

(a) *Specified data, information, and documentation.* The State must require any MCO, PIHP, PAHP, PCCM or PCCM entity to submit to the State the following data:

(1) Encounter data in the form and manner described in § 438.818.

(2) Data on the basis of which the State certifies the actuarial soundness of capitation rates to an MCO, PIHP or PAHP under § 438.4, including base data described in § 438.5(c) that is generated by the MCO, PIHP or PAHP.

(3) Data on the basis of which the State determines the compliance of the MCO, PIHP, or PAHP with the medical loss ratio requirement described in § 438.8.

(4) Data on the basis of which the State determines that the MCO, PIHP or PAHP has made adequate provision against the risk of insolvency as required under § 438.116.

(5) Documentation described in § 438.207(b) on which the State bases its certification that the MCO, PIHP or PAHP has complied with the State's requirements for availability and accessibility of services, including the adequacy of the provider network, as set forth in § 438.206.

(6) Information on ownership and control described in § 455.104 of this chapter from MCOs, PIHPs, PAHPs, PCCMs, PCCM entities, and subcontractors as governed by § 438.230.

(7) The annual report of overpayment recoveries as required in § 438.608(d)(3).

(b) *Additional data, documentation, or information.* In addition to the data, documentation, or information specified in paragraph (a) of this section, an MCO, PIHP, PAHP, PCCM or PCCM entity must submit any other data, documentation, or information relating to the performance of the entity's obligations under this part required by the State or the Secretary.

[81 FR 27853, May 6, 2016, as amended at 82 FR 39, Jan. 3, 2017]

**§ 438.606 Source, content, and timing of certification.**

(a) *Source of certification.* For the data, documentation, or information specified in § 438.604, the State must require that the data, documentation or